

Syphilis Serology (615) 262-6374

Introduction

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. Serological tests greatly aid in the diagnosis of syphilis. Serologic assays used to screen patients for syphilis are non-treponemal tests. The non-treponemal test performed by the Tennessee Department of Health (TDH) Laboratory is the Rapid Plasma Reagin test (RPR). Quantitative RPR results may be used to monitor therapy for *T. pallidum* infections.

Confirmation of reactive RPR screening test results is obtained with specific treponemal tests for syphilis. The *Treponema pallidum*-Particle Agglutination test (TP-PA) is the TDH Laboratory's primary confirmatory test for *T. pallidum*-specific antibody. Suspected biologically false-positive results sometimes produced in the RPR test may be investigated with a TP-PA test. The Fluorescent Treponema Antibody-Absorption -Double Stain Test (FTA-ABS-DS) also detects *T. pallidum*-specific antibody. It is available in limited circumstances. The TP-PA and FTA-ABS-DS **are not screening procedures** and are only performed when required for proper patient management.

The Venereal Disease Research Laboratory (VDRL) test is a non-treponemal test used to test cerebrospinal fluids (CSF). Positive test results are quantitated to aid in monitoring therapy for neurosyphilis. The RPR, TP-PA, and FTA-ABS-DS tests **are** not performed on CSF.

Specimen Acceptance Policy

The TDH Laboratory performs serological procedures for syphilis in support of:

- The state prenatal law.
- The TDH Sexually Transmitted Disease Control Program.
- The private medical community for which the state laboratories serve as reference laboratories.
- Other State agencies for which the TDH Laboratory has contracted or agreed to perform tests.

Testing for syphilis, non-treponemal and treponemal-specific, is available to all health care providers.

Tennessee does not require premarital testing for syphilis.

Syphilis screening tests will be performed for persons who intend to be married in a state requiring premarital syphilis testing. The TDH Laboratory will send appropriate premarital forms for the state in which the wedding will be performed with the results of the laboratory tests. Other states may not accept premarital syphilis testing performed by laboratories other than state public health laboratories such as the TDH Laboratory.

Type of Specimen Required

For the tests performed at the TDH Laboratory, the specimen required, and the application of the test refer to Chart V - 2 SEROLOGICAL TESTS FOR SYPHILIS.

Syphilis Serology (Continued)

Chart V - 2
Serological Tests for Syphilis

	Test	Specimen Required	Application of Test
Nontreponemal Tests	RPR	Whole, clotted blood, serum, or plasma *	Screening (for example, prenatal or STD clinics), monitoring treatment. Performed at Nashville, Knoxville, and Jackson Labs.
	VDRL	Cerebrospinal fluid	Congenital syphilis, central nervous system involvement (neurosyphilis). Performed only at Nashville Lab.
Treponemal Antibody Tests**	TP-PA	Whole, clotted blood or serum	Detection of false-positive RPR results, monitoring of infants for possible congenital syphilis. Performed at Nashville, Knoxville, and Jackson Labs.
	FTA-ABS-DS	Whole, clotted blood or serum	To aid in diagnosis of suspected primary syphilis when the RPR is reactive and the TP-PA test is non-reactive. Performed only at Nashville Lab.

* Plasma can be tested with the RPR test, but plasma is not the preferred specimen. Serum is preferred because it is required for subsequent treponemal antibody tests that may need to be performed after the RPR test is completed. Also, plasma must be tested within 48 hours of collection or the risk of false RPR results is greatly increased.

** Treponemal antibody tests will not routinely be performed on specimens that produce negative results on the screening test (RPR). An exception is that the TP-PA will be performed at the provider's request on specimens that may produce negative RPR results but are from patients (birth to 15-months-old) who may have congenital syphilis.

Specimen Collection

Draw only one syphilis serology blood tube on each patient, even for those requiring a confirmatory test. Additional tubes are unnecessary for two tests and add to the risk of identification errors.

WHOLE, CLOTTED BLOOD OR SERUM

1. Draw at least 5 to 7 ml of blood into a red-stoppered vacuum tube allowing the tube to fill completely. Allow the tube to stand at room temperature to ensure complete clotting of blood. Blood should not be taken for 1 hour after a meal to avoid chylous serum.

Syphilis Serology (Continued)

2. Store the specimen in a refrigerator (2 to 8°C) until it is sent to the laboratory. If serum is to be sent, separate the serum from the blood clot by centrifuging the whole, clotted blood at 1,500 to 2,000 rpms at room temperature for 10 minutes. Pipette the serum into a new red-stoppered vacuum tube or plastic screw-capped vial. Submit at least 2 ml of serum.

PLASMA

Plasma is not a recommended specimen for syphilis testing. It may be submitted (1 to 2 ml) for the screening procedure for syphilis (RPR), but is not a suitable specimen for subsequent TP-PA or the FTA-ABS-DS procedures. Plasma must be tested within 48 hours from the time of collection to produce reliable RPR results.

CEREBROSPINAL FLUID (CSF)

Submit 1 to 2 ml of CSF in a sterile, plastic screw-capped vial.

Specimen Identification

1. **Complete all information on the Syphilis Serology Form PH-1578.** Mark the test requested and include pertinent clinical information with each specimen.
2. Label each specimen with the patient's name and the collection date. Attach the control number on the tear strip to the specimen and secure it with transparent tape. Unlabeled specimens or specimens containing information that does not exactly match the information on the accompanying test request form **will not be tested**.
3. When requesting a TP-PA test, the results of an RPR or other screening procedure must be indicated. Previous TP-PA results must be indicated when requesting the FTA-ABS-DS test.

Shipment of Specimens

1. Packing and shipping specimens to the state public health laboratory requires personnel trained in current regulations. See section I-17 for the ASM guidelines published in November, 2003. Ship it at ambient temperatures.
2. Place the mailing label (PH-0838), return address, and infectious substance (etiologic agent) or clinical (diagnostic) specimen label on the container.
3. Ship blood or serum specimens for the RPR or TP-PA to the TDH Laboratory in **Jackson, Knoxville, or Nashville**. Ship blood or serum specimens for the FTA-ABS-DS test or cerebrospinal fluid specimens for the VDRL test to the Laboratory in **Nashville**.
4. Use first-class postage on US mail.

Interpretation of Laboratory Results

Screening (RPR)

Normal: Non-reactive

Abnormal: Reactive

Confirmatory (TP-PA, FTA-ABS-DS)

Normal: Non-reactive,

Abnormal: Reactive

Positive reactions will occur within 10 to 90 days following exposure or 7 to 10 days after onset of primary lesion.

Biological false-positive RPR results may occur. Possible causes for biological false-positive RPR results:

Narcotic addiction	Hepatitis
Aging	Leprosy
Terminal malignancy	Pregnancy
Viral diseases, e.g., chickenpox, measles, infectious mononucleosis, pneumonia, etc.	Rheumatoid arthritis
Malaria	Systemic lupus erythematosus

Reporting Procedure and Interpretation

Results of the non-treponemal tests for syphilis performed on serum or plasma are available within 1 working day after receipt of the specimen. Results of the TP-PA tests are available within 3 working days. The FTA-ABS-DS results are available within 7 working days. Results of the VDRL test on cerebrospinal fluids are available within 7 working days after receipt of the specimen.

Results of Tests for Syphilis are Reported
Reactive (The RPR and VDRL are quantitated. These results are reported as dils.)
Non-reactive

The results of all specimen requests are reported to the provider who submitted the specimen. In addition, The TDH Sexually Transmitted disease (STD) control, the regional STD control representative, and the health department in the county where the patient lives are sent reports on positive specimens.

For a premarital test, a premarital certificate for the specific state will be sent to the provider with the laboratory results. **Tennessee does not require a premarital syphilis test.**

Syphilis Serology (Continued)

Criteria for Unacceptable Specimens

1. The specimen is not properly identified with the patient's name.
2. The patient identifier on the specimen does not match that on test request form.
3. The specimen is broken or leaked in transit.
4. The specimen is extensively hemolyzed, lipemic (chylous), extremely turbid, or grossly contaminated with bacteria.
5. Whole, clotted blood collected more than 7 days prior to receipt by the laboratory.
6. Plasma collected more than 48 hours prior to receipt by the laboratory.
7. The quantity of the specimen received is not sufficient to allow accurate completion of test requested. (QNS-Quantity Not Sufficient.)
8. Cerebrospinal fluid (CSF) shows evidence of contamination with blood or microbial growth.
9. No test request form was received with the specimen, or no specimen was received with the request form.

Syphilis Serology Form PH-1578

FRONT

SOCIAL SECURITY NO.		TENN CARE NO.		MCO		SYPHILIS SEROLOGY		B2694776	
MEDICARE NO.		RECORD FOLDER NO.		DATE REPORTED		DATE/TIME RECEIVED		LAB NO.	
PATIENTS NAME - LAST, FIRST, MIDDLE				SPOUSE - FIRST NAME		COLLECTION DATE		TYPE OF SPECIMEN SERUM <input type="checkbox"/> CSF <input type="checkbox"/>	
STREET AND NUMBER						PURPOSE OF SPECIMEN			
TOWN		STATE		ZIP		<input type="checkbox"/> SCREENING FOR: <input type="checkbox"/> ROUTINE, <input type="checkbox"/> TREATMENT, <input type="checkbox"/> PRENATAL <input type="checkbox"/> PREMARITAL, (For State of _____) * <input type="checkbox"/> TP - PA (<input type="checkbox"/> REACTIVE SCREEN, <input type="checkbox"/> NON-REACTIVE WITH CLINICAL SIGNS) * <input type="checkbox"/> FTA-ABS (TT-PA Results _____)			
DATE OF BIRTH		RACE		ETHNICITY		SEX		PHONE NO.	
COUNTY NO.		COUNTY NAME		CITY NO.		TEST RESULTS * SEE REVERSE SIDE			
SEND REPORT TO						RPR: <input type="checkbox"/> NON-REACTIVE, <input type="checkbox"/> REACTIVE (Titer) _____ TP-PA: <input type="checkbox"/> NON-REACTIVE, <input type="checkbox"/> REACTIVE _____ FTA-ABS: <input type="checkbox"/> NON-REACTIVE, <input type="checkbox"/> REACTIVE, <input type="checkbox"/> REACTIVE MINIMALLY ** VDRL: <input type="checkbox"/> NON-REACTIVE, <input type="checkbox"/> REACTIVE (Titer) _____ SPECIMEN UNSATISFACTORY <input type="checkbox"/>			
NAME		ADDRESS		CITY		STATE		ZIP CODE	
PH-1578 REV. 6/99		TENNESSEE DEPT. OF HEALTH LABORATORY SERVICES MICHAEL W. KIMBERLY, DR. P.H., DIRECTOR		<input type="checkbox"/> J <input type="checkbox"/> K <input type="checkbox"/> N LABORATORY PERFORMING EXAMINATION		EXAMINED BY:		RDA-1160	

BACK

INSTRUCTIONS	
1.	Use 13 x 100 mm size vacutainer type tube with no additive for submitting syphilis serology specimen. If serum is sent, send the serum in a vacutainer type tube. At least 5 ml of clotted blood or 2 ml of serum should be submitted.
2.	Detach the specimen control number from the form and attach it to the specimen tube and print the patients name on the specimen tube.
3.	Completely fill out the shaded portions of the form.
† = The VDRL test will be used to test CSF. * = The TP-PA and/or FTA-ABS tests will not be used as screening procedures and will be performed only on serum for which a screening procedures has been performed. The TP-PA test is this laboratory's primary test for confirmation of syphilis antibodies and will be performed before the use of the FTA-ABS test is considered. ** = In the absence of historical or clinical evidence of treponemal infection, this test result should be considered equivocal. A second specimen should be submitted for serologic testing.	
TESTING LABORATORY LOCATION CODES	
J	= JACKSON BRANCH LAB, 295 SUMMAR DRIVE, JACKSON, TN - DR. MICHAEL W. KIMBERLY, DIRECTOR
K	= KNOXVILLE BRANCH LAB, 1522 CHEROKEE TRAIL, P.O.BOX 59019, 37950-9019, KNOXVILLE, TN - DR. PHILIP M. BAKER, DIRECTOR
N	= NASHVILLE REFERENCE LAB, 630 HART LANE, NASHVILLE, TN - DR. MICHAEL W. KIMBERLY, DIRECTOR

NOTE: Use the Laboratory Location Codes listed below. New forms are currently undergoing revision.

TESTING LABORATORY LOCATION CODES

J = JACKSON BRANCH LAB, 295 SUMMAR DRIVE, P.O.BOX 849, JACKSON, TN 38302-0849 - MICHAEL W. KIMBERLY, DIRECTOR
 K = KNOXVILLE BRANCH LAB, 1522 CHEROKEE TRAIL, P.O.BOX 59019, 37950-9019, KNOXVILLE, TN - MICHAEL W. KIMBERLY, DIRECTOR
 N = NASHVILLE REFERENCE LAB, 630 HART LANE, NASHVILLE, TN 37247-0801 - DR MICHAEL W. KIMBERLY, DIRECTOR